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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,230	09/13/1999	KEVIN L. GUNDERSON	393382001600	3919

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,230	GUNDERSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 15 December 2005 in which claim 12 was amended and the previous rejections were traversed. The previous rejections in the Office Action dated 30 March 2005 are maintained.

As stated in the previous Office Action, rejection of Claim 18 is maintained because the priority documents do not support the subject matter of this claim. Claim 18 is drawn to arrays arranged in parallel. The priority documents do not disclose parallel arrays. As such the effective filing date for instant Claim 18 is the filing date of the instant application i.e. 09/13/1999.

Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 1-10 and 12-18 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al (WO/97,27317, published 31 July 1997) in view of Southern (U.S. Patent No. 5,700,637, filed 19 April 1994).

Regarding Claim 18, Lockhart et al disclose a method of determining the presence of a mutation in a target polynucleotide, comprising the steps of providing at least two identical polynucleotide probe arrays, each array comprising probes, wherein each probe comprises a double stranded region and a single-stranded n-mer overhang region such that the overhangs in each array constitute a complete set of n-mers (Fig. 13; page 71, lines 9-29 and page 74, lines 1-12) hybridizing the target polynucleotide to said overhangs of probe polynucleotides in one array to generate a target hybridization pattern hybridizing a reference polynucleotide to said overhangs of probe polynucleotides in a second array to generate a reference hybridization pattern and determining the presence of a mutation in the target polynucleotide by normalizing intensity differences of hybridized probes in the reference and target hybridization patterns comparing intensity differences of probes in the reference and target hybridization patterns and determining whether a mutation is present in the target polynucleotide (Example 20, pages 155-158) wherein the target-hybridized array and the reference-hybridized array are compared (page 156, line 29-page 157, line 7) which clearly suggests that the arrays are proximal to each other. But they do not specifically teach that the arrays are arranged in parallel.

However, Southern teaches the similar method wherein the arrays are arranged in parallel i.e. stripes (Column 7, lines 12-22) whereby numerous sequence variations are analyzed simultaneously wherein each stripe corresponds to a different sequence variation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the parallel arrays (i.e. strips) of Southern for the array comparison of Lockhart et al for the expected benefit of analyzing numerous mutations simultaneously as desired in the art (Southern: Column 7, lines 23-26).

Response to Arguments

4. Applicant relies on the priority documents to overcome the above rejection. However, at stated above, the documents upon which applicant relies do not provide support of the parallel arrays of Claim 18. Therefore, the references cited above constitute prior art.

5. Claims 1-10, 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (U.S. Patent No. 5,631,134, filed 5 June 1995) in view of Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996).

Regarding Claim 1, Cantor et al. teach a method of determining the presence of a mutation in a target polynucleotide comprising the steps of providing a polynucleotide probe array wherein each probe comprises a double strand region and a single stranded n-mer overhang region; hybridizing a target polynucleotide to said overhangs in the array to generate a target hybridization pattern; and determining the presence of a mutation in the target polynucleotide by analyzing hybridization patterns (Column 8, lines 1-12) wherein the probes are designed to identify mutations (Column 4, lines 5-8) wherein the a single stranded n-mer overhang region is "preferably" about 4 to 20 nucleotides in length (Column 5, lines 60-65) and wherein the set of probes on the array comprises every possible n-mer (Column 6, lines 3-5). Cantor further provides two examples of complete n-mers (Example 1, Column 12, lines 9-19 & Example 2, Column 12, lines 57-67) wherein the array**s** made are characterized by comparative hybridization of known and unknown sequences (Column 13, lines 14-30). Furthermore, Cantor teaches their arrays are useful diagnostics for mutation identification (Column 4, lines 1-8) that clearly suggest comparative hybridization analysis because to determine a change in sequence (i.e. mutation) the sequence must be compared to an unchanged (wild-type)

sequence. Absent the comparison, a mutation would not be recognized. Cantor et al do not specifically teach hybridization to two arrays and comparison and signal normalization to determine the presence of a mutation. However, it is noted that the instant specification (page 16) teaches this analysis was well known as taught by Rava et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well know two array-hybridization and signal comparison of Rava et al to the sequence analysis of Cantor based on Cantor's desire to analyze sequences to diagnose mutations (Column 4, lines 1-8).

Regarding Claim 2, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9).

Regarding Claim 3, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9). Cantor et al. do not discuss the reference polynucleotide. However, reference polynucleotides were known to one of ordinary skill in the art as discussed above and the skilled practitioner would have known that for comparison purposes, a target and reference polynucleotide would be treated equally i.e. ligated to the probe.

Regarding Claim 4, Cantor et al. teach the overhangs have free 5' ends (Column 12, lines 46-49 and Fig. 1B).

Regarding Claim 5, Cantor et al. teach the overhangs have free 3' ends (Column 12, lines 38-45 and Fig. 1A).

Regarding Claim 6, Cantor et al. teach the n-mer comprises from about 4 to 50 nucleotides (Column 12, lines 57-60).

Regarding Claims 7-9, Cantor et al. teach the mutation is a single nucleotide mutation (Column 10, lines 38-40). Cantor et al. do not teach the single nucleotide mutation is a substitution (Claim 7), a deletion (Claim 8) and an insertion (Claim 9). However, one skilled in the art at the time the claimed invention was made would have known that the single

nucleotide mutations taught by Cantor et al. include the claimed substitution, deletion and insertion mutations.

Regarding Claim 10, Cantor et al teach the method wherein single nucleotide mutations are identified wherein the identification quickly, efficiently and easily detects inherited mutations which cause disease and DNA depended phenotype and somatic variations (Column 10, lines 38-45). Cantor et al. do not teach the target polynucleotide is selected from the recited sequences. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Cantor et al. with the teachings of Cantor et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply the mutation detection teaching of Cantor et al. to sequences known to contain single nucleotide mutations for the obvious benefit of detecting clinically relevant mutations quickly, efficiently and easily as taught by Cantor et al.

Regarding Claim 12, Cantor et al. teach a method of determining relatedness two or more polynucleotides comprising the steps of providing a polynucleotide probe array wherein each probe comprises a double stranded region and a single stranded n-mer overhang region such that the over hangs in each array constitute a complete set of n-mers; hybridizing a target polynucleotide to said overhangs in the array to generate a hybridization pattern and analyzing the hybridization patterns (Column 8, lines 1-10) wherein the a single stranded n-mer overhang region is "preferably" about 4 to 20 nucleotides in length (Column 5, lines 60-65) and wherein the set of probes on the array comprises every possible n-mer (Column 6, lines 3-5).

Cantor further provides two examples of complete n-mers (Example 1, Column 12, lines 9-19 & Example 2, Column 12, lines 57-67) wherein the array**s** made are characterized by comparative hybridization of known and unknown sequences (Column 13, lines 14-30). Furthermore, Cantor teaches their arrays are useful diagnostics for mutation identification (Column 4, lines 1-8) that clearly suggest comparative hybridization analysis because to

determine a change in sequence (i.e. mutation) the sequence must be compared to an unchanged (wild-type) sequence. Absent the comparison, a mutation would not be recognized. Cantor et al do not specifically teach hybridization to two arrays and comparison and signal normalization to determine the presence of a mutation. However, it is noted that the instant specification (page 16) teaches this analysis was well known as taught by Rava et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well know two array-hybridization and signal comparison of Rava et al to the sequence analysis of Cantor based on Cantor's desire to analyze sequences to diagnose mutations (Column 4, lines 1-8)

Regarding Claim 13, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9).

Regarding Claim 14, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9). Cantor et al. do not discuss the reference polynucleotide. However, reference polynucleotides were known to one of ordinary skill in the art as discussed above and the skilled practitioner would have known that for comparison purposes, a target and reference polynucleotide would be treated equally i.e. ligated to the probe.

Regarding Claim 15, Cantor et al. teach the overhangs have free 5' ends (Column 12, lines 46-49 and Fig. 1B).

Regarding Claim 16, Cantor et al. teach the overhangs have free 3' ends (Column 12, lines 38-45 and Fig. 1A).

Regarding Claim 17, Cantor et al. teach the n-mer comprises from about 4 to 50 nucleotides (Column 12, lines 57-60).

Regarding Claim 18, Cantor et al. do not teach parallel arrays. However, Rava teaches parallel arrays (Fig.4).

Response to Arguments

6. Applicant asserts that the comparisons of Cantor sequence comparisons and not hybridization patterns as claimed. Applicant further asserts that Rava as nothing to do with sequence comparison and therefore the cited references do not provide the required motivation for their combination.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cantor specifically teaches analysis of hybridization patterns.

> Hybridization chips can be used to construct very large probe arrays which are subsequently hybridized with a target nucleic acid. Analysis of the hybridization pattern of the chip provides an immediate fingerprint identification of the target nucleotide sequence. Patterns can be manually or computer analyzed, but it is clear that positional sequencing by hybridization lends itself to computer analysis and automation. (Column 7, lines 12-19).

Cantor teaches their arrays are useful diagnostics for mutation identification (Column 4, lines 1-8) that clearly suggest comparative hybridization analysis because to determine a change in sequence (i.e. mutation) the sequence must be compared to an unchanged (wild-type) sequence. Absent the comparison, a mutation would not be recognized. Cantor et al do not specifically teach hybridization to two arrays and comparison and signal normalization to determine the presence of a mutation. Furthermore, Rava et al defines a means for obtaining sequence information is via comparison of hybridization pattern.

> One can obtain sequence information by careful probe selection and using algorithms to compare patterns of hybridization and non-hybridization. This method is useful for sequencing nucleic acids, as well as sequence

> checking. For example, the method is useful in diagnostic screening for genetic diseases or for the presence and/or identity of a particular pathogen or a strain of pathogen. For example, there are various strains of HIV, the virus that causes AIDS. Some of them have become resistant to current AIDS therapies. Diagnosticians can use DNA arrays to examine a nucleic acid sample from the virus to determine what strain it belongs to. (Column 1, lines 36-47)

Therefore, both Cantor and Rava are interested in obtaining hybridization patterns for diagnostic purposes. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the hybridization comparison of Rava to the hybridization of Cantor for the expected benefit increased efficiency provided by parallel processing and analysis as taught by Rava (Abstract and Column 4, lines 27-34).

7. Claims 1-10, 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (U.S. Patent No. 5,631,134, filed 5 June 1995) in view of Brown et al (U.S. Patent No. 5,807,522, filed 7 June 1995) and Augenlicht (U.S. Patent No. 4,981,783, issued 1 January 1991).

Regarding Claim 1, Cantor et al. teach a method of determining the presence of a mutation in a target polynucleotide comprising the steps of providing a polynucleotide probe array wherein each probe comprises a double strand region and a single stranded n-mer overhang region; hybridizing a target polynucleotide to said overhangs in the array to generate a target hybridization pattern; and determining the presence of a mutation in the target polynucleotide by analyzing hybridization patterns (Column 8, lines 1-12) wherein the probes are designed to identify mutations (Column 4, lines 5-8) wherein the a single stranded n-mer

overhang region is "preferably" about 4 to 20 nucleotides in length (Column 5, lines 60-65) and wherein the set of probes on the array comprises every possible n-mer (Column 6, lines 3-5). Cantor further provides two examples of complete n-mers (Example 1, Column 12, lines 9-19 & Example 2, Column 12, lines 57-67) wherein the array**s** made are characterized by comparative hybridization of known and unknown sequences (Column 13, lines 14-30). Furthermore, Cantor teaches their arrays are useful diagnostics for mutation identification (Column 4, lines 1-8), which clearly suggest comparative hybridization analysis because to determine a change in sequence (i.e. mutation) the sequence must be compared to an unchanged (wild-type) sequence. Absent the comparison, a mutation would not be recognized. Cantor et al do not specifically teach hybridization to two arrays and comparison and signal normalization to determine the presence of a mutation.

However, multi-array hybridization and analysis was well known in the art at the time the claimed invention was made as taught by Brown et al who teach that multi-array hybridization provides rapid and convenient mass screenings for diagnostic applications (Column 15, lines 59-67). Furthermore, hybridization signal comparison and normalization was well known in the art as taught by Augenlicht who teach comparison and normalization of arrayed sequences for diagnosis and prognosis of disease (Abstract, and Column 4, lines 5-24 and 36-67).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well know multi-array hybridization and signal comparison of Brown et al and Augenlicht to the sequence analysis of Cantor for the expected benefit of rapid and convenient mass screenings for diagnostic and prognostic applications as taught by Brown et al (Column 15, lines 59-67) and Augenlicht (Abstract, and Column 4, lines 5-24 and 36-67).

Regarding Claim 2, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9).

Regarding Claim 3, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9). Cantor et al. do not discuss the reference polynucleotide. However, reference polynucleotides were known to one of ordinary skill in the art as discussed above and the skilled practitioner would have known that for comparison purposes, a target and reference polynucleotide would be treated equally i.e. ligated to the probe.

Regarding Claim 4, Cantor et al. teach the overhangs have free 5' ends (Column 12, lines 46-49 and Fig. 1B).

Regarding Claim 5, Cantor et al. teach the overhangs have free 3' ends (Column 12, lines 38-45 and Fig. 1A).

Regarding Claim 6, Cantor et al. teach the n-mer comprises from about 4 to 50 nucleotides (Column 12, lines 57-60).

Regarding Claims 7-9, Cantor et al. teach the mutation is a single nucleotide mutation (Column 10, lines 38-40). Cantor et al. do not teach the single nucleotide mutation is a substitution (Claim 7), a deletion (Claim 8) and an insertion (Claim 9). However, one skilled in the art at the time the claimed invention was made would have known that the single nucleotide mutations taught by Cantor et al. include the claimed substitution, deletion and insertion mutations.

Regarding Claim 10, Cantor et al teach the method wherein single nucleotide mutations are identified wherein the identification quickly, efficiently and easily detects inherited mutations which cause disease and DNA depended phenotype and somatic variations (Column 10, lines 38-45). Cantor et al. do not teach the target polynucleotide is selected from the recited sequences. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Cantor et al. with the teachings of Cantor et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply the mutation detection teaching of Cantor et al. to sequences known to contain single nucleotide mutations

for the obvious benefit of detecting clinically relevant mutations quickly, efficiently and easily as taught by Cantor et al.

Regarding Claim 12, Cantor et al. teach a method of determining relatedness two or more polynucleotides comprising the steps of providing a polynucleotide probe array wherein each probe comprises a double stranded region and a single stranded n-mer overhang region such that the over hangs in each array constitute a complete set of n-mers; hybridizing a target polynucleotide to said overhangs in the array to generate a hybridization pattern and analyzing the hybridization patterns (Column 8, lines 1-10) wherein the a single stranded n-mer overhang region is "preferably" about 4 to 20 nucleotides in length (Column 5, lines 60-65) and wherein the set of probes on the array comprises every possible n-mer (Column 6, lines 3-5).

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However, multi-array hybridization and analysis was well known in the art at the time the claimed invention was made as taught by Brown et al who teach that multi-array hybridization provides rapid and convenient mass screenings for diagnostic applications (Column 15, lines 59-67). Furthermore, hybridization signal comparison and normalization was well known in the art as taught by Augenlicht who teach comparison and normalization of arrayed sequences for diagnosis and prognosis of disease (Abstract, and Column 4, lines 5-24 and 36-67).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well know multi-array hybridization and signal comparison of Brown et al and Augenlicht to the sequence analysis of Cantor for the expected benefit of rapid and convenient mass screenings for diagnostic and prognostic applications as taught by Brown et al (Column 15, lines 59-67) and Augenlicht (Abstract, and Column 4, lines 5-24 and 36-67).

Regarding Claim 13, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9).

Regarding Claim 14, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9). Cantor et al. do not discuss the reference polynucleotide. However, reference polynucleotides were known to one of ordinary skill in the art as discussed above and the skilled practitioner would have known that for comparison purposes, a target and reference polynucleotide would be treated equally i.e. ligated to the probe.

Regarding Claim 15, Cantor et al. teach the overhangs have free 5' ends (Column 12, lines 46-49 and Fig. 1B).

Regarding Claim 16, Cantor et al. teach the overhangs have free 3' ends (Column 12, lines 38-45 and Fig. 1A).

Regarding Claim 17, Cantor et al. teach the n-mer comprises from about 4 to 50 nucleotides (Column 12, lines 57-60).

Regarding Claim 18, Cantor et al. do not teach parallel arrays. However, Brown et al (Fig. 9) and Augenlicht (Fig. 1) teach parallel arrays.

Response to Arguments

. Applicant reiterates the deficiencies of Cantor i.e. the reference is concerned with sequence comparisons and not hybridization patterns as claimed. Applicant further asserts that Brown & Augenlicht do not provide the required motivation for their combination. The argument has been considered but is not found persuasive because as cited above, Cantor

specifically teaches that their method utilizes analysis of hybridization patterns (Column 7, lines 12-19).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-10, 12-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 18 of U.S. Patent No. 6,344,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of polynucleotide analysis comprising the same steps of hybridizing polynucleotides from two samples to probe arrays and determining a different in hybridization to analyze the polynucleotide wherein the probes of the arrays comprise double-stranded regions and single-stranded regions. The claim sets merely differ in the arrangement of the limitations within the claim sets and the intended use of the method steps. For example, the instant claims are drawn to determining the presence of a mutation and whether the polynucleotides are identical while the '316 claims are drawn to identifying differences. However, because both sets of claims contain the same method steps, the intended use for the methods does not patentably distinguish the two claim sets. Furthermore, the instant independent claims define the probes as comprising double-stranded

regions and single-stranded regions while dependent Claim 18 provides the same definition of the probes. As such, the claim sets are drawn to methods that are not patentably distinct from each other.

Response to Arguments

Applicant asserts that the instant claims require numerous limitations not found in the '316 patent i.e. the double stranded region and hybridization to overhangs. The argument has been considered but is not found persuasive because Claim 18 of the '316 patent defines the double stranded region and overhang hybridization i.e. hybridization to single stranded variable region.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

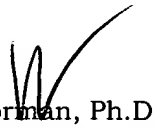
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
February 13, 2006